federal register

FRIDAY, SEPTEMBER 3, 1976

PART III:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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MEDICAL DEVICES

Establishment Registration and Premarket Notification Procedures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 807 and 809]

[Docket No. 76N–0355]

MEDICAL DEVICES

Establishment Registration and Premarket Notification Procedures

The Food and Drug Administration (FDA) is proposing regulations setting forth procedures for the registration of establishments in which devices intended for human use are produced. These proposed regulations would also establish requirements governing the form and manner in which premarket notification submissions are to be sent to FDA, at least 90 days in advance, by any person who proposes to begin commercial distribution in interstate commerce of a device intended for human use. Interested persons have until November 2, 1976 to comment.

The Medical Device Amendments of 1976, Pub. L. 94–295, (hereinafter, the Amendments) became law on May 28, 1976. This legislation, which amended the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 321 et seq.), provides FDA with significant new authority to assure the safety and effectiveness of medical devices intended for human use.

The new legislation added sections 513 through 521 (21 U.S.C. 360c–360k); it amended, among other provisions, section 510 of the act (21 U.S.C. 360) to require manufacturers and other specified producers of medical devices to register each year with FDA and to provide the agency a list of all medical devices manufactured in any establishment that they own or operate. These registration and product listing requirements are similar to and in addition to those applicable to manufacturers of drugs under Part 207 (21 CFR Part 207) and to manufacturers of blood and blood products under Part 607 (21 CFR Part 607).

A new section 510(k) was also added to the registration provisions of the act. This provision requires any person who proposes to begin the introduction into interstate commerce for commercial distribution of a device for human use to notify FDA at least 90 days in advance of such introduction. The purpose of this provision is to afford FDA an opportunity to determine, prior to marketing, whether a device is of a kind for which the premarket approval requirements of the amended act are applicable. If FDA is persuaded that a device which a manufacturer proposes to market is "substantially equivalent" to a device marketed prior to the date of enactment of the Amendments or is "substantially equivalent" to a device marketed subsequently and classified in class I (general controls) or class II (performance standards), the agency is expected to notify the manufacturer promptly that marketing may commence.

Although section 510 of the act governs both establishment registration and product listing, the Commissioner of Food and Drugs is of the opinion that a more orderly implementation of section 510 will be possible if these two functions are accomplished separately during the initial year of implementing the Amendments. This proposed regulation sets out the procedures related to the first function, namely, the registration of establishments producing medical devices. A second proposed regulation will be published in the FEDERAL REGISTER in the near future setting forth the procedures for device listing. The amended act requires, and the Commissioner intends, that both establishment registration and product listing shall be accomplished for all establishments and products before January 1, 1977.

After consideration of all comments received in response to this proposal, a final regulation will be published in the FEDERAL REGISTER. In the interim, this proposal will be used as a guideline to implement section 510 of the act as it applies to establishments that produce medical devices. Because of the short period of time remaining in 1976 to register device establishments, and to provide guidance, with minimum delay, to interested persons on requirements of premarket notification, the Commissioner proposes that the final regulation based on this proposal shall be effective upon its date of publication.

ESTABLISHMENT REGISTRATION

Definitions. Subpart A of proposed Part 807 (21 CFR Part 807) contains definitions relating to establishment registration.

The definition of the term "commercial distribution" in proposed § 807.3(a) specifically excludes internal transfers of a device occurring within an organization, distribution of a device for which there is an approved exemption for investigational use under section 520(g) of the act (21 U.S.C. 360j(g)), and distribution before the effective date of the investigational device regulations of an investigational class III device that is not yet required to have an approved premarket application.

The proposed regulation would require each establishment that registers with FDA to designate an individual within the organization to serve as liaison between the organization and FDA in matters relating to registration. This "official correspondent" would be the person routinely contacted by FDA on matters relating to the registration of device establishments and the listing of device products. This requirement will enable the agency to have one person to contact during the implementation of the medical device registration to resolve any questions or problems that may occur and to permit establishments to designate someone other than the owner or operator to perform this duty.

The term "official correspondent" in proposed § 807.3(d) is defined as the person designated by the owner or operator of an establishment as responsible for performing the duties described in § 807.3(d) (1) through (4). An owner or operator may designate whomever he wishes, including himself, as the "official correspondent." In the event that no one is designated, the owner or operator of the establishment will be considered by FDA to be the "official correspondent."

The use of an official correspondent is intended only to expedite communication between the agency and persons required to register. Therefore, the designation of an individual as the official correspondent for device registration and device listing purposes in no way exempts the owner or operator, or other legally responsible individual, from compliance with all applicable provisions of the act.

Procedures for domestic device establishments. Subpart B of proposed Part 807 sets forth the basic information relating to device establishment registration, such as who must register, the times for registration, and how and when establishments must register. The Commissioner announces that a new Form FD–2891, Initial Registration of Device Establishment, has been developed specifically for the initial registration of device establishments. Every owner or operator of a domestic establishment engaged in, or responsible for, the manufacture, preparation, propagation, compounding, assembly, or processing of a device (including an in vitro diagnostic product) would be required to use this form to register with FDA the principal place of business and all affiliated device establishments. This form will be mailed to all establishments of which FDA has knowledge by August 31, 1976.

New Form FD–2891 contains space for reporting an estimate of the number of device products that the owner or operator will list with FDA, in accordance with the procedures for device listing which will be described in a proposed regulation to be published in the FEDERAL REGISTER in the near future. Each owner or operator is requested to provide the Commissioner with this information so that FDA may prepare for undertaking the listing of devices as required by section 510 of the act. Versions of a device that differ only in size, shape, packaging, or color but are indicated for the same use shall be considered one device for the purpose of estimating the number of device products to be listed.

Upon the completion of the initial registration of device establishments, Form FD–2891 will be replaced by another new form, Form FD–2891(a), Registration of Device Establishment. This form will be the approved form for complying with the annual establishment registration requirements of section 510 of the act and for communicating any change in the organization since the previous registration submission. Form FD–2891(a) will not contain a space for estimating the number of device products because device listing will have been completed.

Registration procedures for foreign device establishments. Subpart C of proposed Part 807 establishes procedures for registration of foreign device establishments that export devices into the United States. These establishments are re-

quested to register with FDA unless they come within one of the exempt classes set out in Subpart D.

Exemptions. Subpart D of proposed Part 807 lists classes of persons who shall be exempt from establishment registration, either by the express terms of section 510(g) of the act or because the Commissioner has concluded that registration of such persons is not necessary for the protection of the public health.

The Commissioner has determined that neither the public nor FDA will achieve any significant benefit by requiring the classes of persons identified in Subpart D to register. The registration of these classes of persons would impose unnecessary, duplicative, costly, and burdensome requirements on such persons, the Government, and the public. The information necessary to determine the manufacturer and the manufacturing site for a particular device generally will be provided by the manufacturer. There is no present need to require that manufacturers of raw materials, practitioners, dispensers, or those individuals who merely handle devices must register with FDA.

The Commissioner reserves the right to future review of the exemptions from establishment registration as provided in Subpart D to determine whether or not such exemptions for certain classes of persons should continue. The exemptions from establishment registration, which are provided for in Subpart D, in no way exempt these classes of persons from complying with other requirements of the act.

PREMARKET NOTIFICATION

Premarket notification procedures. Subpart E of proposed Part 807 establishes requirements governing the form and manner in which premarket notification submissions are to be submitted to FDA, as required by section 510(k) of the act.

The Amendments were intended to protect the public from unsafe and ineffective medical devices, and, at the same time, assure that innovations in medical device technology are not hampered by unnecessary restrictions. The new legislation directs the Commissioner to identify those devices that are simple in design and represent little risk to human health, and those devices that are sophisticated and that may pose risks of injury or ineffective treatment. The classification process prescribed in section 513 of the amended act (21 U.S.C. 360c) provides the primary mechanism by which the Commissioner is to make these determinations.

Section 513, Classification of Devices Intended for Human Use, provides for expert advisory classification panels that shall make recommendations to FDA respecting the appropriate classification for devices intended for human use. Devices on which recommendations have been received must then be classified by FDA into one of three categories defined in terms of the degree of regulation necessary to provide reasonable assurance of safety and effectiveness. The three categories, in ascending order of restrictiveness, are defined in section 513(a)(1) as follows:

Class I—General Controls: This category includes (1) any device for which the general controls set out in the act (i.e., controls relating to adulteration; misbranding; registration; banned devices; notification and repair, replacement, or refund; records and reports; and good manufacturing practices; or some of these) are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (2) any device for which insufficient information exists to determine that general controls are sufficient to provide such assurance, but the device is not represented to be for use in supporting or sustaining life or preventing impairment of health and does not present a potential unreasonable risk of illness or injury.

Class II—Performance Standards: This category includes any device for which general controls are insufficient to provide reasonable assurance of safety and effectiveness of the device and for which there is sufficient information to establish a performance standard that can provide such assurance.

Class III—Premarket Approval: This category includes any device that cannot be classified in class I or II because insufficient information exists to determine the adequacy of either general controls or performance standards to provide reasonable assurance of safety and effectiveness, and the device is purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health or which presents a potential unreasonable risk of illness or injury.

The Amendments contain special provisions relating to the classification of devices not in commercial distribution (i.e., not actually on the market) prior to May 28, 1976, the date of enactment. Any such device (postenactment device) is automatically classified in class III, unless it is of the same type as, and substantially equivalent to, a device on the market before May 28, 1976, or a subsequently marketed device that has been reclassified into class I or II. If a newly marketed device is of the same type as, and substantially equivalent to, a device that is on the market at the time the new device is introduced, it is to be regulated in the same manner as the device already in commercial distribution.

Section 510(k) of the act is intended to assure that manufacturers do not intentionally or unintentionally circumvent the automatic classification into class III of postenactment devices that are not substantially equivalent to previously marketed devices. With the basic information provided by the notification required by section 510(k), the Commissioner is able to assure that such devices are not marketed until they comply with premarket approval requirements of section 515 of the act (21 U.S.C. 360e), or are reclassified into class I or II. It is the responsibility of FDA, as an expert administrative agency, to determine administratively whether a device that is marketed for the first time after May 28, 1976, is substantially equivalent to a previously marketed device. Recent case law and legislative history indicate that it is the responsibility of FDA to determine initially the regulatory classification of products subject to its jurisdiction. See *Ciba, Inc.* v. *Weinberger*, 412 U.S. 640 (1973); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973); House Report No. 94–853, Medical Device Amendments, February 29, 1976, at 13, 37.

The Commissioner believes that the requirement to provide notification to FDA of the marketing of any postenactment device became effective upon enactment of the Amendments, but he recognizes that this position has been the subject of controversy. The Commissioner has elsewhere made clear why his position is both consistent with the amended act and necessary to assure fulfillment of the objectives of Congress in enacting the Amendments. Most manufacturers of medical devices appear to have accepted the Commissioner's interpretation, for in the past 3 months the agency has received more than 480 premarket notifications of intention to market devices for the first time. The agency is currently receiving such notifications at the rate of 50 a week. In the past 3 months, FDA has responded by notifying more than 230 manufacturers that products they proposed to market were substantially equivalent to devices already on the market. Manufacturers can expect such responses to premarket notification to issue on a continuing basis.

The Commissioner expects that manufacturers will continue to notify FDA of their intention to begin marketing of devices in accordance with section 510(k), even though these preposed implementing regulations are not final. He advises that any manufacturer who follows the proposal may assume that his submission will satisfy the minimum requirements of the agency. The Commissioner further advises that he will exercise discretion in evaluating instances in which a manufacturer has failed to provide notice to the agency prior to the promulgation of final regulations prescribing the form and manner of such submissions. In the event that FDA discovers that a manufacturer of a new device which presents a significant risk to users has proceeded to market without notifying the agency, however, prompt judicial enforcement action will be considered.

Under section 510(k) of the act, each person who is obligated to register must notify the Commissioner 90 days prior to introducing a device into interstate commerce for commercial distribution, whether or not the device has been classified pursuant to section 513 of the act. If the device is of a type that has been classified by FDA, the person is required to advise the Commissioner of the class in which the device is classified and any action taken by such person to comply with the applicable requirements of section 514 of the act (performance standards) (21 U.S.C. 360d) or section 515 of the act (premarket approval).

Proposed § 807.81 requires that each person who is obligated to register his establishment pursuant to section 510 of the act and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use must, at least 90 days before introduction or delivery, submit a premarket notification submission to the FDA if any of the following criteria are met:

1. The device is a device that is being introduced into commercial distribution for the first time, that is, the device is not of the same type as or, even if similar, is not substantially equivalent to a device in commercial distribution before May 28, 1976, the date of enactment of the Amendments; or the device is not of the same type as or, even if similar, is not substantially equivalent to a device introduced for commercial distribution after May 28, 1976 and which subsequently has been reclassified into class I or II.

2. The device is being introduced into commercial distribution for the first time by the person required to register, whether or not the device is of the same type as, and substantially equivalent to, a device in commercial distribution (either a pre-enactment device or a post-enactment class I or II device). A person who reintroduces a device that was once in commercial distribution but is subsequently discontinued is required to submit a premarket notification.

3. The device being introduced is a device being currently distributed commercially by the person required to register, but the device has been significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that render a device subject to section 510(k):

a. Any change or modification in the device that could affect the safety or effectiveness of the device, e.g., a change or modification in design, material, chemical composition, energy source, or manufacturing process.

b. Any change or modification in the intended use of the device.

A premarket notification under § 807.81 is not required for a device for which a premarket application under section 515 of the act, or for which a petition to reclassify from class III to class I or II under section 513(f)(2) of the act, is pending before FDA. For such devices, the other submissions will serve the purpose of a notification under section 510(k) of the act.

Proposed § 807.81(c) informs those persons who manufacture electronic products as defined in § 1000.3 (21 CFR 1000.3) of the responsibility to comply with all reporting requirements applicable to electronic products as provided in Part 1002 (21 CFR Part 1002).

Proposed § 807.85 provides an exemption from premarket notification for manufacturers of custom devices. Devices are occasionally ordered from manufacturers by individual health professionals to conform to their own special needs or to those of their patients. In some instances, health professionals themselves develop or alter devices to serve such needs. Examples of devices in which important features are frequently customized are orthopedic, orthotic and other prosthetic devices, specially designed orthopedic footwear, prosthodontic appliances, and ophthalmic devices.

Section 520(b) of the act exempts "custom devices" from applicable performance standards and/or premarket approval requirements to comply with an order of a physician, dentist, or other specially qualified person if (1) the device is not generally available in finished form for purchase or dispensing on prescription, and is not offered for commercial distribution, and (2) the device (a) is either intended for use by a patient named in an order or intended solely for use by a physician, dentist, or other specially qualified person in the course of his practice, and (b) is not generally available to other physicians, dentists, or other designated persons.

Because custom devices are exempted by statute from the premarket approval requirement, a principal purpose for requiring premarket notification is absent. Accordingly, the Commissioner is at this time proposing that custom devices also be exempt from the premarket notification requirements.

Thus, proposed § 807.85 would exempt a manufacturer from the requirement of premarket notification, provided that the device he intended to introduce into interstate commerce for commercial distribution is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution. The proposal would also require that the device be intended for use by a patient named in the order of a physician or dentist (or other specially qualified person), or be intended solely for use by such physician or dentist (or other specially qualified person) or a person under his professional supervision in the course of his professional practice and not generally available to or generally used by other physicians or dentists (or other specially qualified persons).

In the near future, proposed regulations relating to custom devices will be published in the FEDERAL REGISTER. The regulations will designate those persons who are "specially qualified" to order and use custom devices.

Proposed § 807.87 prescribes the type of information that must be included in each premarket notification. Each submission will be reviewed by the FDA to determine if the device intended for introduction or delivery into commercial distribution is automatically classified into class III. To make an informed decision on whether or not the conditions for automatic classification into class III apply, the Commissioner is requiring that each premarket notification submission include the following information:

1. The product name, including both the trade or proprietary name and the common or usual name of the device.

2. The class in which the device is classified under section 513 of the act or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified.

The Commissioner realizes that final classification of devices into appropriate regulatory control categories is not yet complete and that the classification panels will continue for several months to evaluate and make recommendations concerning devices currently in commercial distribution. Because classification information must be submitted with a premarket notification, the Commissioner advises device manufacturers to consult the FEDERAL REGISTER regularly to determine the classification of their devices. Any inquires concerning the classification status of a particular device should be addressed in writing to the Document Control Center (HFK-20), Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910. The written inquiries should bear the notation "Attention: 513(g) Inquiry" on the outside envelope.

3. Action taken by the person required to register to comply with requirements of the act under section 514 (performance standards), or section 515 (premarket approval).

4. Representative labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use.

5. A statement indicating how the device is substantially equivalent to and how it is not substantially equivalent to other products of similar type in commercial distribution, accompanied by supporting data (including clinical data, where necessary). Information is needed by FDA concerning both how a device is similar to and how it is different from other products to aid the agency in determining whether the device is, in fact, substantially equivalent to prior products. The statement may include a list of materials used in the construction of the device and a description of the operating principles of the device.

6. Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device. Information on such a change or modification shall be submitted whether the change or modification is being made to a person's own device or a device marketed by another person.

It is the Commissioner's intention to assure himself that the consequences and/or effects of any planned change in a device have been adequately assessed

prior to introduction of the device for commercial distribution. The supporting data may include data to show that changes in design, material, chemical composition, energy source, or manufacturing process do not compromise the safety and effectiveness of the device. The significance of a change in a device will vary according to the type of device, its complexity, and its intended uses. For example, whether a change in the materials used or in the components of a device is significant, and thus compels a premarket notification, will vary with the device.

Each premarket notification submission received by FDA will be reviewed to determine whether the device intended for introduction for commercial distribution is of the same type as, and substantially equivalent to, a device previously introduced, or is of the same type as, and substantially equivalent to, a device that was first marketed after May 28, 1976, but has subsequently been classified into class I or II. The information required by proposed § 807.87 is essential for FDA to determine whether or not the device intended for introduction into commercial distribution is automatically subject to the requirement of premarket approval.

When the Commissioner finds, on the basis of the information contained in the premarket notification submission, that a device is not of the same type as, or is not substantially equivalent to, a device previously on the market or a device first marketed after May 28, 1976, that has been subsequently classified into class I or II, he will notify the person submitting the premarket notification in writing that the device is immediately subject to premarket approval as provided in section 515 of the act. Similarly, when the Commissioner finds that the device intended for introduction into commercial distribution is of the same type as and substantially equivalent to a device previously in commercial distribution, the Commissioner will promptly advise the affected person in writing of such a finding.

When the Commissioner determines that there is insufficient information in the premarket notification submission to determine whether or not a device is of the same type as, or substantially equivalent to, a device in commercial distribution, he may request additional data regarding the device. Proposed § 807.87(g) would require each person who submits a premarktt notification pursuant to section 510(k) of the act to submit additional information regarding the device upon the written request of the Commissioner. Any request for additional information would advise the person that there is insufficient information contained in the premarket notification submission to make the required determination, and that the person may either file a new premarket notification submission containing the requested information at least 90 days before he intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. Such request will be issued within 30 days from the time of receipt of a premarket notification submission, so that final action can be completed by FDA within 120 days of the original submission if additional information is required to determine substantial equivalence. The Commissioner intends to expedite FDA processing of premarket notification submissions and to minimize disruption of manufacturers' marketing plans.

Proposed § 807.90 prescribes the address and format for submitting a premarket notification. Each submission shall (1) be addressed to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Document Control Center (HFK–20), 8757 Georgia Ave., Silver Spring, MD 20910, (2) be bound in a volume where necessary, (3) be submitted in duplicate on 8½- by 11-inch paper, and (4) contain a cover sheet marked "510(k) Notification." All inquiries regarding a premarket notification submission should be in writing and sent to the address indicated above.

Proposed § 807.95 addresses confidentiality of information. The public release of data and information relating to a premarket notification will be governed by FDA's public information regulations under Part 4 (21 CFR Part 4). Release of such data and information involves two primary considerations. The first consideration is that the information that a manufacturer intends to market a device may have commercial value, and the intent to market a device is evidenced by the submission of a premarket notification. The second consideration is the status of data and information contained in a premarket notification submission.

The Commissioner notes that the intent to market a device is often considered confidential commercial information within the device industry because the premature disclosure of a firm's marketing plans could result in a competitive advantage to the firm's competitors.

For this reason, the Commissioner is proposing in § 807.95 a process whereby the owner or operator of an establishment may request that FDA hold as confidential the intent to market a device. This provision provides an opportunity for the owner or operator to certify in writing to the Commissioner that he considers the intent to market a device to be confidential commercial information; that he has not disclosed the intent to market a device to anyone except employees of the establishment; that he has not disclosed the intent to market a device to scientists, market analysts, exporters, or other individuals who are not paid consultants to the establishment; and that he has taken precautions to protect the confidentiality of his intention to market a device.

This written certification by the owner or operator of an establishment regarding the confidential nature of the intent to market a device shall be included in the premarket notification submission. After the effective date of the final regulations, those premarket notification submissions that do not include a writen certification regarding the confidential nature of the intent to market a device will be available for public disclosure in accordance with FDA's public information regulations. Until the effective date of the final regulations, FDA will regard information on intent to market a device contained in premarket notification submissions as confidential, whether or not there has been compliance with the proposed regulations.

Proposed § 807.95(b) addresses the length of time during which the Commissioner will protect the confidentiality of the intent to market a device. When the Commissioner determines that the owner or operator of an establishment has complied with the procedures described in proposed § 807.95(a), the Commissioner will protect the confidentiality of the intent to market a device for 90 days from the date of receipt of the premarket notification submission by FDA. Proposed § 807.95(b) also provides that the Commissioner will continue to protect the confidentiality of the intent to market a device in those instances when the Commissioner (1) requests in writing additional information regarding the device pursuant to § 807.87(g); or (2) determines that a device intended for introduction into commercial distribution is not substantially equivalent to a device already in commercial distribution by May 28, 1976.

Proposed § 807.95(c) establishes a procedure whereby the owner or operator of an establishment may at the time of submitting a premarket notification submission request that the Commissioner protect the confidentiality of the intention to market a device for more than 90 days from the date of receipt of the premarket notification submission by FDA. The Commissioner anticipates situations where marketing plans may be delayed due to unforseen circumstances. Such circumstances may be an employee or carrier strike, shortages of critical components, unfavorable economic conditions, or other situations.

When the Commissioner determines that (1) an owner or operator has complied with the procedures described in § 807.95(a), and (2) the actual introduction of the device into commercial distribution may take longer than 90 days, and (3) the owner or operator agrees to notify the Commissioner in writing when the device enters into commercial distribution, the Commissioner will protect the confidentiality of the intent to market a device until the receipt of notification by the owner or operator of the establishment that the device has entered into commercial distribution.

The Food and Drug Administration will not disclose any safety and effectiveness data contained in a premarket notification submission (unless it has already been disclosed) before final classification of the product. Other data and information, unless it is exempt from public disclosure in accordance with FDA's public information regulations, will be available for public disclosure. After classification, material that is exempt from public disclosure will continue

to be reatined as confidential. Thus, if submissions contain data or information that is a trade secret or constitutes commercial or financial information that is privileged or confidential within the meaning of § 4.61 (21 CFR 4.61), or is otherwise exempt from disclosure under Part 4, such information will be retained as confidential. After classification, any safety and effectiveness data accompanying a premarket notification submission relating to a device classified in class III (premarket approval) will be retained as confidential. Safety and effectiveness data relating to devices in class I (general controls) or class II (performance standards) will be available for release to the public upon final classification.

Proposed § 807.97 advises a manufacturer who submits a premarket notification in accordance with Subpart E of Part 807 that submission of a premarket notification and subsequent determination by the Commissioner that the device is substantially equivalent to a device in commercial distribution before May 28, 1976, or substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been classified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval because of complying with the premarket notification regulations is misleading and constitutes misbranding. The Commissioner is emphasizing that any review of a premarket notification by FDA does not in any way imply that the device is in compliance with any other pertinent sections of the act.

A conforming amendment to § 809.20 (21 CFR 809.20) is also being proposed. Additional minor cross-reference conforming amendments to §§ 4.100 and 4.116 (21 CFR 4.100 and 4.116) will be made when the regulations in this proposal are published in final form.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. The Commissioner has also carefully considered the inflation impact of the proposed regulation as required by Executive Order 11821, OMB Circular A-107, and the Guidelines issued by the Department of Health, Education, and Welfare, and no major inflation impact has been found. Copies of the FDA environmental and inflation impact assessments are on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301(p), 501, 502, 510, 701(a), 52 Stat. 1049–1051 as amended, 1055, 86 Stat. 562, 90 Stat. 576–580 (21 U.S.C. 331(p), 351, 352, 360, 371(a))) and under authority delegated to him (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

1. By adding new Part 807 to read as follows:

PART 807—ESTABLISHMENT REGISTRATION FOR MANUFACTURERS OF DEVICES

Subpart A—General Provisions

Sec.
807.3 Definitions.

Subpart B—Procedures for Domestic Device Establishments

807.20 Who must register.
807.21 Times for establishment registration.
807.22 How and where to register establishments.
807.25 Information required or requested for establishment registration.
807.26 Amendments to establishment registration.
807.35 Notification of registrant.
807.37 Inspection of establishment registrations.
807.39 Misbranding by reference to establishment registration or to registration number.

Subpart C—Registration Procedures for Foreign Device Establishments

807.40 Establishment registration for foreign manufacturers of devices.

Subpart D—Exemptions

807.65 Exemptions for device establishments.

Subpart E—Premarket Notification Procedures

807.81 When a premarket notification submission is required.
807.85 Exemption from premarket notification for custom device manufacturers.
807.87 Information required in a premarket notification submission.
807.90 Format of a premarket notification submission.
807.95 Confidentiality of information.
807.97 Misbranding by reference to premarket notification.

AUTHORITY: Secs. 301(p) 501, 502, 510, 701(a), 52 Stat. 1042–1043 as amended, 1049–1050 as amended, 1055, 90 Stat. 576–580 (21 U.S.C. 331(p), 351, 352, 360, 371(a))).

Subpart A—General Provisions

§ 807.3 Definitions.

(a) "Commercial distribution" means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between registered domestic establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use pursuant to section 520(g) of the act and Part 812 of this chapter; or

(3) Any distribution of a device, before the effective date of Part 812 of this chapter, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act:

Provided, That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved premarket approval application as provided in section 515 of the act.

(b) "Establishment" means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.

(c) "Manufacture, preparation, propagation, compounding, assembly, or processing" of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:

(1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

(2) Initial distribution of imported devices; or

(3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution.

(d) "Official correspondent" means the person designated by the owner or operator of an establishment as responsible for the following:

(1) The annual registration of the establishment;

(2) Contact with the Food and Drug Administration for device listing;

(3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner; and

(4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm's establishments.

(e) "Owner or operator" means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

Subpart B—Procedures for Domestic Device Establishments

§ 807.20 Who must register.

(a) Any owner or operator of an establishment, not exempt under section 510(g) of the act or Subpart D of this part, engaging in the manufacture, preparation, propagation, compounding, assembly or processing of a device intended for human use is required to register. The term device includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. Such owner or operator is required to register his name, places of business, and all such establishments whether or not the output of such establishments enter interstate commerce. The registration requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured for him for subsequent commercial distribution;

(2) Manufacturers for commercial distribution a device either for himself or for another person;

(3) Repackages or relabels a device; or

(4) Initially distributes a device imported into the United States.

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) No registration fee is required. Registration does not constitute an admission or agreement or determination that a product is a "device" within the meaning of section 201(h) of the act.

§ 807.21 Times for establishment registration.

The owner or operator of an establishment entering into or presently engaged in an operation defined in § 807.3(c) shall register such establishment within 15 days of receiving Form FD–2891, Initial Registration of Device Establishment. If the owner or operator of the establishment has not previously entered into such operation, registration shall follow within 5 days after the submission of a premarket notification submission pursuant to section 510(k) of the act. Owners or operators of all establishments so engaged shall register annually between November 15 and December 31.

§ 807.22 How and where to register establishments.

The first registration of a device establishment shall be on Form FD–2891, Initial Registration of Device Establishment. Forms are obtainable on request from the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Registration and Listing Section (HFK–124), 8757 Georgia Ave., Silver Spring, MD 20910, or from the Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FD–2891(a), Registration of Device Establishment, which will be furnished by the Food and Drug Administration before November 15 of each year to establishments whose device registration for that year was validated pursuant to § 807.35(a). The completed form shall be mailed to the above address before December 31 of that year.

§ 807.25 Information required or requested for establishment registration.

(a) Form FD–2891, Initial Registration of Device Establishment, and form FD–2891(a), Registration of Device Establishment, are the approved forms for initially providing the information required by the act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including post office ZIP code, all trade names used by the establishment, and the business trading name of the owner or operator of such establishment.

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing of imported devices and identify any other FDA registries in which the establishment is registered.

(c) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment he registers and to furnish this information to the Food and Drug Administration upon request.

(d) Each owner or operator shall provide the name of an official correspondent who will serve as a point of contact between the Food and Drug Administration and the establishment for matters relating to the registration of device establishments and the listing of device products. All future correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to this official correspondent. In the event no person is designated by the owner or operator, the owner or operator of the establishment will be the official correspondent.

(e) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the act.

§ 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FD–2891(a), Registration of Device Establishment. This information shall be submitted shall be submitted within 5 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

§ 807.35 Notification of registrant.

(a) The Commissioner will provide to the official correspondent, at the address listed on the form, a validated copy of Form FD–2891 or Form FD–2891(a) (whichever is applicable) as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

(b) Owners and operators of device establishments, who also manufacture or process blood or drug products at the same establishment, shall also register with both the Bureau of Biologics and the Bureau of Drugs as appropriate. Blood products shall be listed with the Bureau of Biologics, Food and Drug Administration, pursuant to Part 607 of this chapter, and drug products shall be listed with the Bureau of Drugs, Food and Drug Administration, pursuant to Part 207 of this chapter.

(c) Although establishment registration is required to engage in the device activities described in § 807.20, validation of registration in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

§ 807.37 Inspection of establishment registrations.

A copy of the Form FD–2891, Initial Registration of Device Establishment, and FD–2891(a), Registration of Device Establishment, filed by the registrant will be available for inspection pursuant to section 510(f) of the act, at the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Registration and Device Listing Section (HFK–124), 8757 Georgia Ave., Silver Spring, MD 20910. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of registration number or location of a registered establishment will be provided.

§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Registration Procedures for Foreign Device Establishments

§ 807.40 Establishment registration for foreign manufacturers of devices.

Foreign device establishments that export devices into the United States are requested to register in accordance with the procedures of Subpart B of this part, unless exempt under Subpart D of this part.

Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g) (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or

laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, clinical laboratories, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments dispensing or selling devices in the regular course of business at the retail level. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) Persons who handle devices but make no revisions to such devices or their immediate containers, such as wholesalers or warehousers.

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer and whose major responsibility is to render a service necessary to provide the consumer with a device; for example, a hearing aid dealer, optician, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary function is to dispense or provide a previously manufactured device to a consumer.

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to section 510 of the act and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use must, unless exempt under § 807.85, at least 90 days before introduction or delivery, submit a premarket notification submission to the Food and Drug Administration if the device meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or if it is the same type, is not substantially equivalent to a device in commercial distribution before May 28, 1976, or it is not the same type as, or, if it is the same type, is not substantially equivalent to a device introduced for commercial distribution after May 28, 1976 that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device is the same type as and is substantially equivalent to a device in commercial distribution. A person who reintroduces a device that was once in commercial distribution, but is subsequently discontinued, is required to submit a premarket notification.

(3) The device being introduced is a device that the person currently has in commercial distribution, but that has been significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) Any change or modification in the device that could affect (increase or decrease) the safety or effectiveness of the device, e.g., a change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) Any change or modification in the intended use of the device.

(b) A premarket notification under this Subpart E is not required for a device for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this Part 807, owners or operators of device establishments which manufacture electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

§ 807.85 Exemption from premarket notification for custom device manufacturers.

A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and such device meets one of the following conditions:

(a) It is intended for use by a patient named in such order of such physician or dentist (or other specially qualified person); or

(b) It is intended solely for use by such physician or dentist (or other specially qualified person) or a person under his professional supervision in the course of the professional practice of such physician or dentist (or other specially qualified person), and is not generally available to or generally used by other physicians or dentists (or other specially qualified persons).

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The product name, including both the trade or proprietary name and the common or usual name of the device.

(b) The class in which the device is classified under section 513 of the act, or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for such person's determination that the device is not so classified.

(c) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards or section 515 for premarket approval.

(d) Representative labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use.

(e) A statement indicating how the device is substantially equivalent to and how it is not substantially equivalent to other products of similar type in commercial distribution, accompanied by data to support the statement. This information may include a list of materials used in the construction of the device and a description of the operating principles of the device.

(f) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could affect the safety or effective ness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(g) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to determine whether the device is substantially equivalent to a device in commercial distribution, and that the owner or operator may either submit a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act.

§ 807.90 Format of a premarket notification submission.

Each premarket notification submission pursuant to Part 807 shall be submitted in accordance with this section. Each submission shall:

(a) Be addressed to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Document Control Center (HFK–20), 8757 Georgia Ave., Silver Spring, MD 20910. All inquiries regarding a premarket notification submission should be in writing and sent to the above address.

(b) Be bound into a volume or volumes, where necessary.

(c) Be submitted in duplicate on 8½-by 11-inch paper.

(d) Contain a cover sheet marked "510(k) NOTIFICATION."

§ 807.95 Confidentiality of information.

(a) The existence of a premarket notification submission under Part 807 will generally be available for public disclosure by the Food and Drug Administration in accordance with Part 4 of this chapter. The person submitting a premarket notification submission may, however, request that the Food and Drug Administration hold as confidential commercial information the intent to market a device in 90 days. Any such person who wishes to request that the Food and Drug Administration consider an intent to market a device as confidential commercial information shall certify in writing to the Commissioner:

(1) That the person considers his intent to market the device to be confidential commercial information;

(2) That neither the person nor, to the best of his knowledge, anyone else has disclosed his intent to market the device to anyone except employees of the establishment;

(3) That the person has not disclosed his intent to market the device to scientists, market analysts, exporters, or other individuals who are not paid consultants to the establishment; and

(4) That the person has taken precautions to protect the confidentiality of the intent to market the device. The written certification by the person regarding the confidential nature of the intent to market a device shall be included in the premarket notification submission.

(b) Where the Commissoner determines that the person has complied with the procedures described in paragraph (a) of this section, and the Commissioner agrees that the intent to market the device is confidential commercial information, the Commissioner will protect the confidentiality of the intent to market a device for 90 days from the date of receipt of the premarket notification submission by the agency, except that the Commissioner will continue to protect the confidentiality of an intent to market a device when the Commissioner (1) requests in writing additional information regarding the device pursuant to § 807.87(g), or (2) determines that the device intended for introduction into commercial distribution is not substantially equivalent to a device already in commercial distribution by May 28, 1976.

(c) A person may request in the premarket notification submission that the Commissioner protect the confidentiality of the intent to market a device for more than 90 days from the date of receipt of the premarket notification submission by the Food and Drug Administration. When the Commissioner determines that (1) a person has complied with the procedures described in paragraph (a) of this section, and the Commissioner agrees that the intent to market the device is confidential commercial information, (2) the person has reason to believe that the actual introduction of the device into commercial distribution may take longer than the intended 90 days, and (3) the person agrees to provide the Commissioner with written notification as to when the device enters into commercial distribution, the Commissioner will protect the confidentiality of the intent to market a device until the receipt of notification by the person that the device has entered into commercial distribution.

(d) Data or information submitted with, or incorporated by reference in, a premarket notification (other than safety and effectiveness data that have not been disclosed to the public) shall immediately be available for disclosure by the Food and Drug Administration, unless exempt from public disclosure in accordance with Part 4 of this chapter. Upon final classification, data and information relating to safety and effectiveness of a device classified in class I (General Controls) or class II (Performance Standards) shall be available for public disclosure. Data and information relating to safety and effectiveness of a device classified in class III (Premarket Approval), which has not been released to the public, shall be retained as confidential unless such data and information become available for release to the public in accordance with criteria set forth in Part 814 of this chapter relating to premarket approval.

§ 807.97 Misbranding by reference to premarket notification.

Submission of a premarket notification by a manufacturer in accordance with Subpart E of this part, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

2. In Part 809, by amending § 809.20 by revising paragraph (a) to read as follows:

§ 809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

(a) *Registration and product listing.* Any person who owns or operates any establishment engaged in the manufacture, preparation, compounding, or processing of an in vitro diagnostic product should register such establishment and list such product(s) in accordance with the procedures established under Part 807 of this chapter, except that regulation and listing is not required or requested at this time for general purpose laboratory reagents and equipment for which labeling requirements are specified in § 809.10(d).

* * * * *

Interested persons may, on or before November 2, 1976, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: August 30, 1976.

JOSEPH P. HILE,
Acting Associate Commissioner for Compliance.

[FR Doc.76-25877 Filed 9-2-76;8:45 am]